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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,531	02/05/2004	Cindy A. Sprecher	00-42D1	5582

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,531	SPRECHER ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *11-18 and 22-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Election/Restrictions:

1a. Applicant's election of Group I, (claims 1-10 and 19-21), in the reply filed on 16 June 2006 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Claims:

1b. Claims 1-45 are pending, of which elected claims 1-10 and 19-21, will be searched and examined, Claims 11-18 and 22-45 are withdrawn from consideration by the Examiner as they are drawn to non-elected invention.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10 June 2004 has been received and complies with the provisions of 37 CFR §1.97 and §1.98. The references in parent application serial number 09/892,949 have been considered as to the merits.

Specification:

3a. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser executable code, on at least page 92, line 92, page 93, line 1 and page 114, lines 5-6. Applicant is required to delete the embedded hyperlink and/or other form of browser executable code. Please examine the specification carefully for any other hyperlinks in the text and delete them. See MPEP § 608.01.

3b. The Brief Description of the Drawings should be corrected. Figure 1 is shown in three panels (Figure 1A , Figure 1B and Figure 1C) and Figure 2 is shown in two panels (Figure 2A and Figure 2B) , however, the Brief Description of the Drawings only reflects one Figure 1 and Figure 2. Appropriate correction of the Brief Description of the Drawings which reflects Figure 1A, Figure 1B, Figure 1C, Figure 2A and Figure 2B is required.

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

4a. Claims 1-10 and 19-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-10 and 19-21 of the instant invention are directed to an isolated polypeptide comprising and amino acid sequence having at least 95% identity with amino acid resides 33-662 or residues 33-532,of SEQ ID NO:54, wherein the polypeptide stimulates inflammation upon bidning zcytor17 ligand, or a composition comprising said polypeptide and a pharmaceutically acceptable carrier.

The specification describes the claimed nucleic acid as encoding a novel receptor and designates it "Zcytor17" (see page 17, lines 13-16). The instant specification states that the claimed polypeptide having the structure of a class I cytokine receptor subfamily that includes gp130, LIF, IL-2, oncostatin M receptor and

WSX-1 receptor, (see page 16, lines 5-17 and page 30, lines 17-25). The specification also states that the Zcytor17 has been shown to be up-regulated in monocytes and that one of skill in the art would recognize that agonists of zcytor17; are useful. For example, depressed migration of monocytes has been reported in populations with a predisposition to infection, such as newborn infants, patients receiving corticosteroid or other immunosuppressive therapy, and patients with diabetes mellitus, burns, or AIDS, (see page 60, lines 10-15). The specification also Moreover, one of skill in the art would recognize that antagonists of zcytor17 are useful, for example, in atherosclerotic lesions, monoblastic leukemia, (page 61, lines 1-13). However, although the specification asserts that the claimed polypeptide binds to a zcytor17 ligand, it does not demonstrate such. Examples 10 and 18 disclose a procedure for identifying ligands which activate the claimed receptor, however, the instant specification does not show that the claimed polypeptide binds to a zcytor17 ligand or whether the claimed polypeptide is involved in any of the asserted diseases.

The specification discloses that thrombopoietin signals through a chimera which comprises the intracellular domain of zcytor17 receptor and the extracellular domain of MP1 (TPO receptor), resulting in a 9-13 fold proliferation over background of BaF3 cells. However, relevant art teaches that soluble form of Mp1 binds to exogenous TPO and blocks its activity, (see Kaushansky et al, Oncogene Vol. 21, 2002, pages 3359-3367, especially page 3360, column 1). Therefore, since the soluble Mp1 receptor alone is known to bind and interfere with TPO action, it is unclear what is the role of the

intracellular domain of zcytor17 receptor in the chimera used in Example 6, page 117, line 29).

Dillon et al (nature immunology, Vol. 5, Number 7, July 2004, pages 752-760) teach interleukin 31 signals through a receptor, which is composed of IL-31 receptor A (IL-31 Rav4, instant SEQ ID NO:54) and oncostatin M receptor, (see abstract and page 753). Dillon et al also teach that further investigation of signal transduction pathways mediated by IL-31Rav4 will be needed to determine the biological function of this putative receptor in primary cells (see page 758, first paragraph). Therefore, although the instant specification speculates that the claimed polypeptide is a receptor of r zcytor17 and that it is involved in various disparate diseases, it appears that the claimed polypeptide was an uncharacterized polypeptide at the time the instant invention was filed (26 June 2001), because its biological function has not been appreciated in 2004, as evidenced by Dillon et al. Further research would have to be conducted to determine the biological significance of the polypeptide of SEQ ID NO:54, however, this further research is part of the act of the invention, and unless it has been undertaken, the invention is incomplete.

Therefore, the instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4b. Claims 1-10 and 19-21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not define the physiological role of the Zcytor17 polypeptide (SEQ ID NO:54), neither does it establish a link between the claimed polypeptide and a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that is insufficient to establish a specific or substantial utility for the claimed invention.

Furthermore, even if the instant claims had a specific and substantial asserted utility or a well established utility, absent factual evidence, a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed

biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research (see Wells, 1990, Biochemistry 29:8509-8517).

Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the sequence which are tolerant to change (e.g. such as by substitutions or deletions), and the nature and extent of changes that can be made in these positions. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the structure and still maintain sufficient activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on structure and function, and the breadth of the claims which fail to recite any structural or functional limitations,

undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Priority:

5. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is entitled to the effective filing date of 26 June 2001, which is the filing date of the parent application 09/892,949. The invention is not supported by the disclosure of any of the other priority applications. The prior applications disclose the polypeptide of SEQ ID NO:54, however, none of the other parent applications satisfy the requirements under 35 U.S.C. §112, first paragraph, because they fail to teach how to use the claimed invention.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 06/26/2001, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 06/26/2001.

Claim Rejections - 35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-2, 4, 7, 8, 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Maeda et al, (WO 00/75314, dated 14 December 2000).

Instant claims 1-4 are drawn to an isolated polypeptide comprising amino acid of SEQ ID NO:54, or an amino acid sequence having at least 95% sequence identity with 33-662 or 33-532 of SEQ ID NO:54, wherein the polypeptide stimulates inflammation upon binding zcytor17 ligand.

Maeda et al. disclose an isolated polypeptide that shares 100% identity with the polypeptide comprising the amino acid set forth in SEQ ID NO:54 recited in the instant claims. Please see attached sequence query Appendix A. Regarding the recited activity, even if Applicants establishes that the claimed invention possesses the recited activity, the polypeptide disclosed by Maeda et al would inherently possess such activity, because a product and its properties cannot be separated.

Therefore, Maeda et al. reference anticipates instant claims 1-2, 4, 7, 8, 9, in the absence of any evidence to the contrary.

Claim Rejections under 35 U.S.C. §103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4, 5-6, 10 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young et al in view of Capon et al., U.S. Patent Number 5,116,964.

The teachings of Maeda et al. are discussed above. Maeda et al. do not teach chimeric polypeptide comprising the polypeptide of Maeda's invention fused to a heavy chain constant region of an immunoglobulin.

Capon teaches fusion proteins comprising immunoglobulin polypeptide fused to "ligand binding partners", which are defined as including hormones and growth factors (see column 2, lines 14-19). At column 4, lines 38-43, Capon states that the immunoglobulin (Ig) fusions of the invention "serve to prolong the in vivo plasma half-life of the ligand binding partner..." and "facilitate its purification by protein A". Also taught are recombinant materials for making such a fusion protein, vectors and expression; see columns 15-16. Preferred embodiments include sequences including the hinge regions of IgG-1, -2, -3 or -4, IgA, IgE, IgD and IgM, see column 14, lines 40-45 (the first domain of the constant region can be omitted). The preferred species of Ig was human, see claims 8-9. Capon states that the DNA sequences for the Ig chains were well known in the art at the time the invention was made, see column 15 beginning at line 40.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the proteins of Thornton et al. to make fusion proteins as taught by Capon et al. The person of ordinary skill in the art would have been motivated to make the modification in view of Capon's disclosure that fusion proteins facilitate purification of desired proteins. With respect to claims 19-21 it would have been obvious to produce the polypeptide of Maeda et al and a pharmaceutically acceptable carrier, because it is routine to do so, for proper therapeutic use. Accordingly, the invention, taken as a whole, is prima facie obvious over the cited prior art.

Conclusion:

8. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
06 August 2006

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